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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,601	04/28/2006	William Suttle Peters	13634.4011	3338

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ORRICK, HERRINGTON & SUTCLIFFE, LLP
IP PROSECUTION DEPARTMENT
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EXAMINER

BEHRINGER, LUTHER G

ART UNIT	PAPER NUMBER
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3766

MAIL DATE	DELIVERY MODE
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03/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,601	Applicant(s) PETERS ET AL.	
	Examiner LUTHER G. BEHRINGER	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to the communication received on 02/02/2009 concerning application no. 10/595601 filed on 04/28/2006.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claim(s) 39 – 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kapp et al. (US 4,256,094, herein Kapp)** in view of **Krueger (US 3,552,383)**.

With regard to **claim 39**, Kapp discloses a heart assist device wherein said heart assist device comprising: a pump for generating fluid pressure, **26**; an inflatable cuff, **12**, for applying said pressure to blood in a blood vessel; a fluid, *water*, for transmitting said pressure between said pump for generating fluid pressure and said inflatable cuff for applying said pressure (Fig. 1; Col. 1, ll. 65 – Col. 2, ll. 7), but fails to disclose positioning a microphone within said fluid, the microphone being adapted to detect heart sounds in said blood vessel.

However, Krueger discloses the use of a microphone in conjunction with a occluding arm cuff (Figs. 1 & 2; Col. 2, ll. 12 – 46). Krueger places his microphone on the brachial artery of the patient.

4. A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of microphone utilized to record appropriate physiological sounds on which to base actuation of therapy. Thus, it would have been obvious to a

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person having ordinary skill in the art at the time of the invention to modify Kapp to include a microphone and associated recordings as a basis for therapy as taught by Krueger, since it is well known that heart sounds correspond to the opening and closing of aortic valves, and the use of such as a basis for therapy would be a reliable indicator of the pumping cycle of the heart.

5. Further, regarding the placement of the microphone within a fluid as discussed in **claim 39 and 41**, one of ordinary skill in the art at the time of the invention would be aware that sound waves travel faster in an incompressible media, versus a compressible one (approximately four times faster in water, than in air at 20° C). In addition, when sound waves cross between different mediums, refraction of the sound wave occurs as well. The examiner is taking **Official Notice** of these facts. As a result, it would have been obvious to one having ordinary skill in the art at the time of the invention to place the microphone in a media that would be directly associated with the characteristic of interest, in this case the fluid as it interacts with heart sounds, due to the increased speed with which those sounds may be sensed and responded to.

Regarding **claim 40**, Kapp in view of Krueger discloses wherein said heart sounds detected by the microphone are utilized in controlling the operation of said heart assist device (Krueger: Abstract).

With regard to **claim 42**, Kapp in view of Krueger discloses wherein said pressure is directly applied to the exterior of said blood vessel (Kapp: Fig. 1).

Regarding **claim 43**, Kapp in view of Krueger discloses wherein said pressure is applied to the exterior of an artery but is silent as to the location of that artery.

6. Kapp in view of Krueger discloses the claimed invention except for specifically placing the cuff on the aorta. It would have been obvious to one having ordinary skill in the art at the time the invention was made to place the cuff on the aorta, an artery, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

With regard to **claim 44**, Kapp in view of Krueger discloses wherein said pressure is applied to said inflatable cuff and said inflatable cuff in turn applies said pressure to the exterior of said blood vessel (Kapp: Fig. 1).

Regarding **claim 45**, Kapp in view of Krueger discloses wherein said heart assist device initiates a change in its pulsatile state in response to electrical detection of an R-wave in a patient's heart rhythm and returns to the pulsatile state it had before the preceding R-wave in response to said microphone detecting said heart sound created by closure of the patient's aortic valve (Krueger: Col. 2, ll. 12 – 46).

With regard to **claim 46**, Kapp in view of Krueger discloses wherein said inflatable cuff includes a flexible membrane, *elastic liner*, and said flexible membrane applies said pressure to the blood in the blood vessel (Kapp: Fig. 1; Col. 3, ll. 7 – 19).

Regarding **claim 47**, Kapp in view of Krueger discloses wherein said fluid is a liquid (Kapp: Col. 1, ll. 65 – Col. 2, ll. 7).

With regard to **claim 48**, Kapp in view of Krueger discloses wherein said fluid is a gas (Kapp: Fig. 3; Col. 4, ll. 18 – 56).

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 form.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUTHER G. BEHRINGER whose telephone number is (571)270-3868. The examiner can normally be reached on Mon - Thurs 9:00 - 6:30; 2nd Friday 9:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

/Luther G Behringer/
Examiner, Art Unit 3766